WHAT IS CLAIMED IS:

1. A system for managing clinical trials, the system comprising:

a Web client, wherein the Web client can access the Web via a Web browser;

a client;

a server, wherein the Web client can access the server via a Web connection and the client can access the server via a connection other than the Web connection; and

a patient records database, wherein the patient records database can be accessed by the server and the patient records database is logically partitioned and distributed based on a role in the clinical trials process of a user accessing the information.

2. The system of claim 1, wherein the Web client comprises one or more of a computer, a cellular telephone, and a personal data assistant.

3. The system of claim 1, wherein the client comprises one or more of a computer, a cellular telephone, and a personal data assistant.

4. The system of claim 1, wherein the user comprises one of sponsor, regulator, investigator, site, patient, and monitor.

5. The system of claim 1, wherein the server provides applications one or more of comprising:

a trial design application, wherein the trial design application allows a clinical trial to be designed, developed, and customized;

a trial conduct application, wherein the trial conduct application manages ongoing operations of the clinical trial;

a trial monitoring application, wherein the trial monitoring application provides information about the ongoing operations of the clinical trial at a moment in time during the clinical trial;

a trial analysis application, wherein the trial analysis application provides information about the results of the clinical trial up to the time the trial analysis application is accessed;

a trial closure application, wherein the trial closure application performs a function to close-out the clinical trial;

a portal application, wherein the portal application provides a user interface accessible through the Web connection;

a commercial off-the-shelf software application, wherein the commercial off-the-shelf software application integrates external software used by the system;

a good clinical information application, wherein the good clinical information application assures that collected data is compliant with industry regulations and standards, is in accordance with an organizational workflow and the clinical trial critical path, adheres to data integrity standards, and is maintained in accordance with security and privacy standards;

an applications interface application, wherein the applications interface application allows the client to access the system; and

a security application, wherein the security application allows user-defined password-protected access to the data and assures the security and integrity of the data while maintaining the compatibility with industry standards and regulations.

6. The system of claim 5, further comprising a trial submission application, wherein the trial submission application assembles information required for regulatory submissions and generates reports for regulatory reporting.

7. The system of claim 5, wherein the industry standards and regulations comprise one or more of the Health Level 7, 21 CFR Part 11, Health Insurance Portability and Accountability Act (1996), and American Society for Testing and Materials requirements.

8. The system of claim 5, wherein the trial design application comprises a dictionary and standards component, wherein the dictionary and standards component enables interfaces between the system and relevant dictionaries and standards comprising one or more of common data elements, common toxicity criteria, MedDRA codes, ICD9/10 codes, IMT codes, and Common Data Interchange Standards Consortium.

9. The system of claim 7, wherein the trial design application further comprises a clinical development planner component, wherein the clinical development planner component assists in identification of clinical trial candidates for development and helps in creating target product profiles.

10. The system of claim 7, wherein the trial design application further comprises a protocol manager component, wherein the protocol manager component allows the definition of all elements of the clinical trial in a collaborative manner with tight document control.

11. The system of claim 5, wherein the trial conduct application comprises one or more of:

a change management system component, wherein the change management system component allows for the implementation of clinical quality assurance and control through the ability to revise, version, and track modifications and approvals on controlled documents comprising one or more of protocols, informed consents, case reports forms, investigative brochures, patient materials, and advertising and marketing materials;

a subject registration manager component, wherein the subject registration manager component registers patients and profiles them against clinical trial inclusion and exclusion criteria for appropriate patient recruitment, allows for the collection of demographic, payer, referring physician, and emergency information as one portion of the complete clinical trial-related electronic medical record, and captures information about the referring physician for the purposes of evaluating investigative site performance, gathering patient population characteristics, and maintaining a two-way flow of information pertaining to the patients medical condition and progress through the trial;

a financial account manager component, wherein the financial account manager component enables gate-keeping of medical billing to assure appropriate billing practices in the context of clinical research;

an investigation agent manager component, wherein the investigational agent manager component allows the capture of all drug distribution, tracking, disposition, accountability, transfer, and return in accordance with regulations and a clinical trial protocol;

a patient evaluation manager component, wherein the patient evaluation manager component facilitates interpretive summaries, diagnosis code assignment, and treatment code

assignment to allow for assurance of compliance with the clinical trial protocol, proper study visit documentation, streamlined serious adverse event reporting, and clinical outcome evaluation;

a treatment regimen manager component, wherein the treatment regimen manager component allows for a standardized mechanism for treatment courses and dose escalations in accordance with algorithms that are configured in accordance with the clinical trial protocol;

a clinical data import manager component, wherein the clinical data import manager component allows interface with radiology imaging systems for import of radiographic data and diagnostic interpretations, medical information systems for import of medical data, and medical information systems for import of laboratory data for the clinical trial;

an auto encoding component, wherein the auto encoding component codes disease categories and toxicity data through access to current global libraries and coding algorithms; and

an adverse event manager component, wherein the adverse event manager component collects and tracks all adverse events in the clinical trial process.

12. The system of claim 11, wherein the trial conduct application further comprises an encounter scheduler and tracker component, wherein the encounter scheduler and tracker component integrates the scheduling of clinical trial-related visits with routine physician office visits and captures physician-patient encounter data from each clinical trial-related visit.

13. The system of claim 5, wherein the trial monitoring application comprises one or more of :

a database snapshot generator component, wherein the database snapshot generator component enables access to data for real-time clinical trial status monitoring at definable intervals for resource allocation, trend analysis, decision support, and interim analysis; and

a subject status manager component, wherein the subject status manager component ascertains the status of all subjects in the clinical trial and captures reasons subjects leave the clinical trial.

14. The system of claim 12, wherein the trial monitoring application further comprises a monitor and auditor manager component, wherein the monitor and auditor manager component assures compliance with regulations requiring specific monitoring and auditing of the clinical trial process.

15. The system of claim 12, wherein the trial monitoring application further comprises a case report form manager component, wherein the case report form manager component allows the design and tracking of paper and electronic case report forms.

16. The system of claim 5, wherein the trial analysis application comprises a clinical outcome manager component, wherein the clinical outcome manager component generates interim and final clinical trial status reports.

17. The system of claim 15, wherein the trial analysis application further comprises an executive information manager component, wherein the executive information manager component allows for the monitoring of key executive vital signs, data analysis, and business intelligence.

18. The system of claim 5, wherein the applications interface application comprises:

an application programming interface component, wherein the application programming interface component enables external applications to communicate with the system; and

an XML Data Pump component, wherein the XML Data Pump component allows import and export of data in XML format to and from the patient records database.

19. The system of claim 18, wherein the applications interface application further comprises a mobile connectivity component, wherein the mobile connectivity component allows mobile devices to enter and retrieve data as the client.

20. The system of claim 18, wherein the applications interface application further comprises a patient records manager component, wherein the patient records manager component allows external electronic medical records to be added to the clinical trials process, which provides the system with demographic information.

21. A method for reporting clinical trials information comprising:

creating reporting requirements for a stakeholder;

extracting data from the system based on the reporting requirements;

validating the data against regulations and standards;

creating information from the data based on what is known about the stakeholder; and

displaying the information to the stakeholder.

22. The method of claim 21, wherein the stakeholder comprises one of sponsor, regulator, investigator, site, patient, and monitor.

23. A method for monitoring events within a system for managing clinical trials, the method comprising:

performing an event in a clinical trials protocol;

checking the event against business logic rules, industry regulations, and industry standards; and

alerting at least one stakeholder of the event.

24. A method for scheduling and tracking appointments of a clinical trial subject comprising:

designing a schedule of subject visits based on a clinical trial protocol;

enrolling a subject based on inclusion and exclusion criteria of the clinical trial protocol;

scheduling subsequent visits for the subject;

providing alerts that the enrolled subject should be sent reminders in advance of subsequent visits of the subject;

generating a checklist upon a visit by the subject;

documenting the checklist of items completed and not completed after the visit by the subject;

documenting cancelled and missed visits by the subject;

dropping the subject if a number of visits cancelled and missed exceeds a threshold;

notifying the subject when the number of visits cancelled and missed exceeds the threshold; and

documenting the dropping of the subject when the number of visits cancelled and missed exceeds the threshold.

25. The method of claim 24, wherein the subsequent visits comprise one or more of an office visit, laboratory tests, x-ray tests, procedures, and preparation for procedures.

26. The method of claim 24, wherein the checklist comprises one or more of prompting a principal investigator review and signature, generating patient instructions, generating a coordinator checklist, checking laboratory results, checking pathology results, checking microbiology results, and checking study reports.

27. The method of claim 24, wherein the threshold of visits cancelled and missed comprises three visits.

28. The method of claim 24, wherein the notifying the subject comprises sending a certified letter to the subject.

29. A method for assuring good clinical information in scheduling and tracking the appointments of a clinical trial subject comprising:

checking a designed schedule of subject visits for consistency with a clinical trial protocol and rules of informed consent;

collecting subject information in a manner compliant with industry regulations and standards;

checking the collected subject information against inclusion and exclusion criteria of business logic rules;

changing subject information coding to indicate enrolled and non-enrolled subjects;

checking lead time of a scheduled visit against all other scheduled visits for conflicts;

assuring that reminder calls are made and documented;

assuring that due diligence is shown and documented in regard to cancelled and missed visits by subjects;

assuring that proper methods are used to drop a subject from the clinical trial;

assuring the proper notice is given to a dropped subject; and

assuring the subject information of a dropped subject is properly identified in the system.

30. A method for alerting and reporting in scheduling and tracking the appointments of a clinical trial subject comprising:

generating subject instructions at time of scheduling a subject visit;

generating a checklist automatically at beginning of the subject visit;

notifying at least one stakeholder at the beginning of the subject visit;

alerting at least one stakeholder if a scheduled visit is missed or cancelled;

alerting at least one stakeholder before a scheduled subject visit;

generating a checklist to track proper compliance with follow-up procedures; and

alerting at least one stakeholder if the subject is dropped for exceeding a threshold of missed and cancelled visits.

31. The method of claim 29, wherein the stakeholder comprises one of sponsor, regulator, investigator, site, patient, and monitor.

32. A method for producing good clinical information within a system for managing clinical trials, the method comprising:

assuring that clinical information is collected in compliance with regulatory requirements;

assuring that the clinical information is collected in accordance with a proper organization workflow;

assuring that the clinical information is collected according to a clinical trial critical path;

assuring data integrity of the clinical information;

assuring the security of the clinical information; and

assuring the privacy of the clinical information.

33. The method of claim 32, wherein the assuring the information is collected in compliance with regulatory requirements comprises assuring consistency with regulations from one or more of the International Conference on Harmonization Good Clinical Practice, the Code of Federal Regulations, the Office of Human Research Protections, and the National Institutes of Health.

34. The method of claim 32, wherein assuring that the clinical information in accordance with a proper organization workflow comprises one or more of integrating business rules, integrating clinical trials processes' connectivity, assuring proper sequencing of critical path elements, assuring proper change management, assuring proper logistics, and collecting the information in accordance with the approved study protocol.

35. The method of claim 32, wherein the assuring data integrity of the clinical information comprises one or more of validating that the information is accurate, determining that the information is relevant to the study being conducted, assuring that the information is in a standardized coding system, assuring that the information is normalized, verifying that the information is complete, assuring that the information is uncorrupted, and assuring that the information is unaltered.

36. The method of claim 32, wherein the assuring the security of the clinical information comprises preventing access to the information by unauthorized non-stakeholders.

37. The method of claim 32, wherein the assuring the privacy of the clinical information comprises preventing access to the information by unauthorized stakeholders.

38. A method for closing-out a clinical trial comprising:

providing a first report of treatment allocation for all enrolled subjects;

providing a second report on all used and unused investigational products;

locking a clinical trial database after completion of all case report forms;

performing a final analysis on the locked clinical trial database;

notifying at least one stakeholder of completion of the clinical trial; and

drafting a final clinical study report.

39. A method for presenting information to stakeholders within a system for managing clinical trials, the method comprising:

creating a digital dashboard for a stakeholder;

displaying a category of information common to all stakeholders on the digital dashboard; and

displaying a category of information specific to the stakeholder on the digital dashboard.

40. The method of claim 39, wherein the stakeholder comprises one of sponsor, regulator, investigator, site, patient, and monitor.

41. The method of claim 39, wherein the category of information common to all stakeholders comprises one or more of an email application, links to Web sites, references to trial information, announcements, and alerts.

42. The method of claim 39, wherein the category of information specific to a sponsor stakeholder comprises one or more of study documents, site performance, action items, financial metrics, good will metrics, safety records, and sponsor performance metrics.

43. The method of claim 39, wherein the category of information specific to a regulator stakeholder comprises one or more of study documents, site performance, action items, and site adverse events.

44. The method of claim 39, wherein the category of information specific to an investigator stakeholder comprises one or more of monitoring schedule, action items, monthly and daily schedule, site performance metrics, queries, milestones, and site adverse events.

45. The method of claim 39, wherein the category of information specific to a site stakeholder comprises one or more of monitoring schedule, action items, site statistics, site performance metrics, waiting response, safety training, pending investigational new drug reports, special handling information, efficacy summary, and safety summary.

46. The method of claim 39, wherein the category of information specific to a patient stakeholder comprises one or more of investigator profile, information about the study disease, patient record, reminders, instructions, and study documents.

47. The method of claim 39, wherein the category of information specific to a monitor stakeholder comprises one or more of multi-site monitoring, milestones, adverse events, action items, queries, and multi-site performance metrics.